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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/612,072	07/03/2003	David Lewis	239775US0DIV	3477
22850 7590 02/15/2007 OBLON, SPIVAK, MCCLELLAND, MAIER & NEUSTADT, P.C. 1940 DUKE STREET ALEXANDRIA, VA 22314			EXAMINER HAGHIGHATIAN, MINA	
			ART UNIT	PAPER NUMBER
			1616	
SHORTENED STATUTORY PERIOD OF RESPONSE		NOTIFICATION DATE	DELIVERY MODE	
3 MONTHS		02/15/2007	ELECTRONIC	

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

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<b>Office Action Summary</b>	<b>Application No.</b> 10/612,072	<b>Applicant(s)</b> LEWIS ET AL.	
	<b>Examiner</b> Mina Haghighatian	<b>Art Unit</b> 1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 19 October 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 11-14, 16-19, 21-26, 28-32, 35-46, 48 and 49 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 11-14, 16-19, 21-26, 28-32, 35-46, 48 and 49 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>07/19/06</u> . | 6) <input type="checkbox"/> Other: _____  |

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### DETAILED ACTION

Receipt is acknowledged of the IDS filed on 07/19/06 and the Amendments and Remarks filed on 10/19/06. Claims 11, 19 and 26 have been amended and claims 15, 20, 27, 33, 34 and 47 have been cancelled while no new claims have been added. Accordingly, claims 11-14, 16-19, 21-26, 28-32, 35-46, 48 and 49 remain pending.

### *Claim Rejections - 35 USC § 103*

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

**Claims 11-14, 16-19, 21-26, 28-32, 39-46, 48-49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cutie (6,129,905) in view of Tzou et al (5,776,433).**

Cutie teaches aerosol formulations for mucosal and/or topical administration containing one or more drugs and a sugar as a dispersant in a pharmaceutically acceptable propellant. Metered dose inhalers suitable for delivering such formulations are also disclosed. Cutie discloses that in an aerosol drug formulation the drug may be **dissolved in the propellant** (col. 1, lines 24-29). In a **solution** formulation, a cosolvent may be added to enhance drug dissolution (col. 2, lines 3-10). The formulations may contain **ethanol** up to 5% of the formulation (col. 5, lines 5-9). Drugs which may be administered via the said formulations include flunisolide, beclomethasone, triamcinolone, **budesonide** (col. 4, lines 25-35). The said formulations may contain

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excipients such as antioxidants (col. 5, lines 31-34). The formulations may be filled into conventional aerosol containers using conventional filling equipment well known to those skilled in the art (col. 5, lines 40-45). Examples such as example 5, 7, 8 and 11 show formulations comprising an active agent such as triamcinolone or flunisolide, ethanol and propellant. Cutie lacks disclosure on specific antioxidants such as butylated hydroxyanisole and the canister specifics.

Tzou teaches flunisolide aerosol formulations comprising a therapeutically effective amount of flunisolide in solution with ethanol and a propellant selected from the group consisting of 1,1,1,2-tetrafluoroethane, 1,1,1,2,3,3,3-heptafluoropropane and a mixture thereof used for the treatment of bronchial asthma. The formulations may be delivered by a metered dose inhaler with a canister that is inert to flunisolide (see abstract). Tzou discloses that NASALIDE® nasal solution comprises excipients such as butylated hydroxyanisole (col. 1, lines 17-26). It is also disclosed that in the formulations of the invention, the flunisolide is fully dissolved and the formulation is free from undissolved flunisolide (col. 2, lines 36-40). Aerosol canisters equipped with conventional valves, preferably metered dose valves (col. 3, lines 45-50). Conventional aerosol canisters can be used to contain a formulation of the invention. The formulations are contained within a glass aerosol vial or an aluminum aerosol vial having an interior formulation chamber coated with a resin that is inert to flunisolide and preferably does not absorb flunisolide from the formulation. Suitable resins for coating

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the formulation chamber include materials commonly employed as interior can coatings, such as epoxy resins (e.g. epoxy-phenolic resins and epoxy-urea formaldehyde resins).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made given the general formulations of Cutie on solution formulations of corticosteroids, such as budesonide, antioxidants and propellants for inhalation and treatment of respiratory disorders to have looked in the art for specific antioxidants and specific aerosol canisters that would improve stability and efficiency of the inhaled formulations as taught by Tzou. Furthermore it would have been obvious to a person of ordinary skill in the art to have chosen other antioxidants such as ascorbyl palmitate, since all antioxidants are known and have been used by those skilled in the art.

**Claims 35-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cutie (6,129,905) in view of Tzou et al (5,776,433) as applied to claims 11-14, 16-19, 21-26, 28-32, 39-46, 48-49 above, and further in view of Riebe et al (6,558,651).**

Cutie and Tzou, discussed above, lack specific disclosure on the inner surface of the metered dose being composed of anodized aluminum or stainless steel.

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Riebe et al teaches aerosol formulations and the suitable canisters for metered dose inhalers. The formulations may be filled into canisters capable of withstanding the vapor pressure of the propellant, such as plastic, plastic-coated glass bottle or preferably a metal can, for example an **aluminum can which may be anodized**, lacquer-coated and/or plastic coated, which container is closed with a metering valve. The MDI can may be a coated metal can such as **aluminum or stainless steel** (see col. 5, lines 20-55).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made given the general formulations of the combined references of Cutie and Tzou on solution formulations of corticosteroids for inhalation and treatment of respiratory disorders filled into conventional metered dose inhalers to have looked in the art for specific aerosol canisters such as coated interiors, that would improve stability and efficiency of the inhaled formulations as taught by Riebe et al.

### ***Double Patenting***

The provisional rejection of claims 11-14, 16-19, 21-26, 28-32, 35-46, 48 and 49 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims of copending Application No. 10/244,519 is maintained.

Copending Application No. 10/244,519 has been allowed, but not yet issued. Also a favorable Interference Decision was made on 08/01/06.

***Response to Arguments***

Applicant's arguments, filed 10/19/06, with respect to claims 11-49 have been fully considered and are persuasive with regards to certain rejections. The rejections made over Cutie '419; Rovee '100; Keller (WO 9834595) and Radhakrishnan '528 have been withdrawn.

Applicant however, did not respond to the rejections made over Cutie et al (6,129,905) in view of Tzou et al (5,776,433).

Cutie et al '905 teaches solutions of active agents such as budesonide, cosolvents such as ethanol, propellants such as HFA 134a and excipients such as antioxidants. A sugar is used as a dispersant. Tzou '433 teaches solutions of flunisolide, ethanol, propellant and discloses specific antioxidants useful for the said solution formulation. Riebe et al teaches the specifics of the device. Thus it is considered that the combination of the three references cited meets all the limitations of the claimed invention. Again it is noted that the Applicants arguments are on Cutie '419 and not on Cutie '905 (see Remarks, page 10).

Applicant argues that Tzou teaches the presence of water and sorbitan trioleate as well as cetylpyridinium chloride in a suitable concentration which enhances the chemical stability of certain flunisolide HFA formulations. Applicant then argues that Tzou does not provide any teaching on how the problem of chemical stability of budesonide in an HFA and ethanol solution can be solved. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., the problem of stability) are not

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recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). In other words, this is not commensurate with the scope of claims. Instant claims are drawn to 1) an aerosol formulation comprising budesonide, a propellant and an antioxidant (claim 11), 2) a metered dose inhaler comprising the formulation of claim 11 (claim 19), and 3) a method of treating a bronchial disorder comprising administering the formulation of claim 11 (claim 26). Thus the presence of water or sorbitan trioleate are not excluded and the method of stabilizing the said formulations is not a point of consideration here. It has been shown that Tzou teaches what is missing from the teachings of Cutie '905.

Applicant also argues that Riebe '651 is concerned with the problem of adhesion or deposition with regards to recrystallized form of salbutamol sulphate, and does not solve the problem of chemical degradation of budesonide. Again, this is not commensurate with the scope of claims (see above).

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992).

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

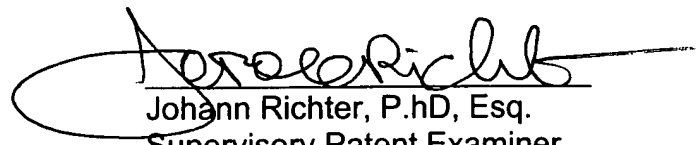
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mina Haghighatian whose telephone number is 571-272-0615. The examiner can normally be reached on core office hours.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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January 16, 2007

  
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